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IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF CALIFORNIA SAN JOSE DIVISION

APPLE INC., et al.) Case No.: 5:20-cv-06128-EJD	
Plaintiffs,	 Defendant's Notice of Motion for Summary Judgment, Motion for Summary Judgment and Opposition to Plaintiffs' Motion for Summary Judgment 	
V. KATHERINE K. VIDAL, in her official capacity as Under Secretary of Commerce for Intellectual Property and Director, United States Patent and Trademark Office,	Hon. Edward J. Davila Hearing Set for December 7, 2023; 9:00 a.m.	
Defendant.	ý	

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NOTICE OF MOTION AND MOTION

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2	PLEASE TAKE NOTICE that on December 7, 2023, at 9:00 a.m., in Courtroom 4, 5th
3	Floor, before the Honorable Edward J. Davila, Defendant Katherine K. Vidal, Under Secretary of
4	Commerce for Intellectual Property and Director, United States Patent and Trademark Office
5	("USPTO"), will and hereby does move this Court for an order entering judgment for USPTO
6	pursuant to Federal Rule of Civil Procedure 56. This Motion is based on this Notice, the points
7	and authorities in support of the motion, and on such oral argument as the Court may permit. As
8	the following memorandum of points and authorities demonstrates, the Fintiv factors (as defined
9	infra) are a lawful exercise of agency discretion which the agency may adopt without notice-and-
10	comment rulemaking. Summary judgment should be entered for Defendant.
11	STATEMENT OF ISSUES
12	Whether the non-dispositive, non-exhaustive factors set forth in Apple Inc. v. Fintiv, Inc.,
13	IPR2020-00019, 2022 WL 2126495, Paper 11 (P.T.A.B. Mar. 20, 2020), constitute a general
14	statement of policy, or non-substantive rule, that the Director of the USPTO ("Director") could
15	lawfully adopt without notice-and-comment rulemaking.
16	BACKGROUND
17	I. THE AMERICA INVENTS ACT
18	In 2011, Congress passed the Leahy-Smith America Invents Act ("AIA"), Pub L. No.
19	112-29, 125 Stat. 284 (2011), which, among other things, modified the USPTO's longstanding
20	authority to review the patentability of existing patent claims. See Cuozzo Speed Techs., LLC v.
21	Lee, 579 U.S. 261, 268 (2016). The most common mechanism of reviewing patents under the
22	AIA is "inter partes review," or "IPR." Id. By filing an IPR petition, "a third party [may] ask the
23	U.S. Patent and Trademark Office to reexamine the claims in an already-issued patent and to

cancel any claim that the agency finds to be unpatentable in light of prior art." Id. at 2136; see

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also 35 U.S.C. §§ 311, 312 (setting forth procedural and substantive requirements for a petition to institute IPR proceedings). The Director "may not authorize an inter partes review to be instituted unless the Director determines that the information presented in the petition . . . and any response filed . . . shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least [one] of the claims challenged in the petition." 35 U.S.C. § 314(a); see also 35 U.S.C. § 313 (patent owner may file preliminary response)

"Congress has committed the decision to institute interpartes review to the Director's unreviewable discretion." United States v. Arthrex, Inc., 141 S. Ct. 1970, 1977 (2021) (citing Thryv, Inc. v. Click-To-Call Techs. LP, 140 S. Ct. 1367, 1372-73 (2020)); see also Oil States Energy Servs., LLC v. Greene's Energy Grp., 138 S. Ct. 1365, 1371 (2018). The AIA contains "no mandate to institute review." Cuozzo Speed Techs., 579 U.S. at 273; see also SAS Inst., Inc. v. Iancu, 138 S. Ct. 1348, 1356 (2018). The Director's determination whether to institute review is "final and nonappealable." 35 U.S.C. § 314(d). By regulation, the Director has delegated her authority to decide IPR petitions to the Patent Trial and Appeal Board. ("the Board."). 37 C.F.R. § 42.4(a).

Congress also gave the Director the authority to establish regulations that "govern the conduct of proceedings in the Office." 35 U.S.C. § 2(b)(2)(A). In the AIA, Congress required the Director to prescribe regulations relating to 13 distinct aspects of the IPR process, including "setting forth the standards for the showing of sufficient grounds to institute a[n inter partes] review." 35 U.S.C. § 316(a)(2); see also 37 C.F.R. 42.108(c). Notably, Congress did not instruct the Director to promulgate regulations setting forth the standards for the exercise of her

discretion to deny institution of IPR proceedings. See id.; see also Cuozzo Speed Techs, 579 U.S. at 267.

II. REGULATORY FRAMEWORK

Congress gave the Director responsibility for "providing policy direction and management supervision" for the USPTO. 35 U.S.C. § 3(a)(2)(A). The Director also has independent authority as a Board member. *See* 35 U.S.C. § 6(a). The Director can exercise this supervision in a variety of ways, such as overseeing Board executives, publishing guidance materials (*e.g.*, the Trial Practice Guide), issuing memoranda on the handling of recurring issues before the Board, and designating Board decisions as precedential. Pursuant to this authority, the Director issued Standard Operating Procedure 2 ("SOP 2") in 2018, addressing the Director's ability to provide policy direction to the Board through precedential opinions.²

Although there is no requirement to do so, in 2020, the Director requested and received comments from stakeholders and the public in response to the Request for Comments on Discretion to Institute Trials Before the Patent Trial and Appeal Board. 85 Fed. Reg. 66502 (Oct. 20, 2020). The Director has also taken the additional step of issuing an Advanced Notice of Proposed Rulemaking ("ANPRM") in April 2023 to gather more data and feedback on, among other things, the agency's discretion to institute IPR. *See* Changes Under Consideration to Discretionary Institution Practices, Petition Word-Count Limits, and Settlement Practices for America Invents Act Trial Proceedings Before the Patent Trial and Appeal Board, 88 Fed. Reg. 24503 (April 1, 2023), at https://www.govinfo.gov/content/pkg/FR-2023-04-21/pdf/2023-08239.pdf

² On July 24, 2023, SOP 2 Revision 11 replaced and superseded the 2018 SOP 2 Revision 10.

Revision 11 retires the Precedential Opinion Panel process, and otherwise makes no substantive

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As SOP 2 explains, the Director can designate a Board opinion (or portion thereof) as precedential. SOP 2. "A precedential decision is binding Board authority in subsequent matters involving similar facts or issues." SOP 2 at 7. Regardless of the procedural path a case has taken, "[n]o decision or portion thereof may be designated as precedential or informative pursuant to [SOP 2] without the Director's approval[,]" and the Director can de-designate an opinion at any time. 3 Id. at 6, 8. Further, SOP 2 does not "limit the Director's authority to issue, at any time and in any manner, [other] policy directives[,] . . . such as policy directives concerning the interpretation and implementation of statutory provisions." *Id.* at 1.

III. THE NHK-FINTIV FACTORS

At issue in this case are two USPTO decisions that the Director designated as precedential: NHK Spring Co., Ltd. v. Intri-Plex Techs., Inc., No. IPR2018-00752 (Paper 8) (P.T.A.B. Sept. 12, 2018), and Apple Inc. v. Fintiv, Inc., IPR2020-00019 (Paper 11). Both decisions concern how, when the Board exercises the Director's delegated authority, the Board should weigh existing, parallel district court proceedings addressing the validity of the same or similar patent claims. In NHK, the Board noted that efficiency weighed in favor of denying review when a "district court proceeding will analyze the same issues and will be resolved before

change to the precedential designation process described in Revision 10. Citations here are to Revision 11. Available at

https://www.uspto.gov/sites/default/files/documents/20230724 ptab sop2 rev11 .pdf ³ Although they are not at issue in this case, "[i]nformative decisions set forth Board norms that should be followed in most cases, absent justification, although an informative decision is not binding authority on the Board." SOP 2 at 7.

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any trial on the [IPR] [p]etition concludes." *NHK Spring Co., Ltd.*, IPR2018-00752 at 19-20. In *Fintiv*, the Board expanded on *NHK*, explaining that "an early trial date" is one "non-dispositive factor[] considered for institution under 35 U.S.C. § 314(a)" and "should be weighed as part of a 'balanced assessment of all relevant circumstances of the case, including the merits." *Fintiv*, Paper 11 at 5 (quoting the Consolidated Trial Practice Guide (Nov. 2019) at 58).

The Board in *Fintiv* also identified six factors it had previously considered "relat[ing] to whether efficiency, fairness, and the merits support the exercise of authority to deny institution in view of an earlier trial date in the parallel proceeding[s]." *Id.* at 6.⁴ The *Fintiv* factors are:

- (1) whether the court granted a stay or evidence exists that one may be granted if a proceeding is instituted;
- (2) proximity of the court's trial date to the Board's projected statutory deadline for a final written decision;
- (3) investment in the parallel proceeding by the court and the parties;
- (4) overlap between issues raised in the petition and in the parallel proceeding;
- (5) whether the petitioner and the defendant in the parallel proceeding are the same party; and
- (6) other circumstances that impact the Board's exercise of discretion, including the merits.

Id. The Director's designation of *Fintiv* as precedential means that the Board must consider the *Fintiv* factors in future institution decisions involving parallel district court proceedings. *See* SOP 2 at 7. In June 2022, the Director issued a guidance memorandum revising the *Fintiv*

⁴ Because *Fintiv* followed the reasoning of *NHK*, the non-dispositive factors announced in *Fintiv* effectively subsume *NHK*'s holding. Defendant therefore most frequently frames Plaintiffs' claims as being challenges to the *Fintiv* factors, although the defects in Plaintiffs' challenges apply equally to *NHK*.

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⁵ Available at

analysis. See United States Patent & Trademark Office, Memorandum, Interim Procedure for Discretionary Denials in AIA Post-Grant Proceedings with Parallel District Court Litigation (June 21, 2022) ("June 2022 Guidance"). In this memorandum, the Director made four updates to the Board's consideration of IPR petitions. Specifically, she directed that:

- (1) the Board should not discretionarily deny institution under *Fintiv* when a petition presents compelling evidence of unpatentability;
- (2) the Board should not discretionarily deny institution under *Fintiv* when the parallel proceeding is before the U.S. International Trade Commission;
- (3) the Board should not discretionarily deny institution under *Fintiv* when a petitioner stipulates not to pursue, in a parallel district court proceeding, the same grounds as in the petition or any grounds that could reasonably have been raised in the petition; and
- (4) when considering the second *Fintiv* factor directed to the proximity of the district court's trial date, the Board should consider the median time from filing to disposition of the civil trial for the district in which the parallel litigation resides.

See June 2022 Guidance, at 3-8.

IV. PROCEDURAL HISTORY

Plaintiffs are companies who allege they often file *inter partes* review petitions in response to patent infringement lawsuits. Am. Compl. for Decl. & Injunctive Relief ("Am. Compl.") ¶¶ 24-27, 62, ECF No. 54. Some of those IPR petitions have not been instituted by the Board after consideration of the *Fintiv* factors in light of co-pending district court proceedings.

https://www.uspto.gov/sites/default/files/documents/interim proc discretionary denials aia par allel district court litigation memo 20220621 .pdf

Id. ¶¶ 56-61. Plaintiffs brought this suit to set aside the Director's designation of *Fintiv* and *NHK* as precedential and to foreclose USPTO's reliance on the *Fintiv* factors when making discretionary institution decisions. *Id.* ¶¶ 56-63.

Plaintiffs' Amended Complaint brought three claims challenging the *Fintiv* factors, alleging (1) the Director lacked authority to designate the decision as precedential; (2) the *Fintiv* factors are arbitrary and capricious; and (3) the *Fintiv* factors are invalid because the Director could have adopted them only by notice-and-comment rulemaking. *Id.* ¶ 82-95. This Court previously granted Defendant's Motion to Dismiss, concluding that although Plaintiffs had standing to pursue their claims, Section 314(d) barred review of all three counts. *See* Order Granting Motion to Dismiss; Terminating Motion for Summary Judgment ("Order"), ECF No. 133, at 10-11. On appeal, the Federal Circuit affirmed in part and reversed in part, agreeing with this Court that Counts I and II are nonjusticiable. *Apple Inc. v. Vidal*, 63 F.4th 1, 17-18 (Fed. Cir. 2023), *petition for cert. filed* (August 15, 2023). But the panel reversed and remanded on Count III, which alleges USPTO was required to undertake notice-and-comment rulemaking. *Id.* Defendant now moves for summary judgment on Count III and opposes Plaintiffs' motion for summary judgment.

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ARGUMENT

Instituting IPR proceedings is a discretionary act by the Director. *Arthrex*, 141 S. Ct. at 1977; *Oil States Energy Servs.*, 138 S. Ct. at 1371. And the AIA has "no mandate to institute review," *Cuozzo Speed Techs.*, 579 U.S. at 273; *see also SAS Inst., Inc.*, 138 S. Ct. at 1356 (2018). The Director is "permitted but never compelled to institute IPR," and is "free . . . to determine that for reasons of administrative efficiency an IPR will not be instituted, as agencies generally are free, for similar reasons, to choose not to initiate enforcement proceedings." *Mylan*

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Labs. Ltd. v. Janssen Pharm., N.V., 989 F.3d 1375, 1382 (Fed. Cir. 2021), cert. denied, 142 S. Ct. 874 (2022). The decisions that Plaintiffs challenge here—NHK and Fintiv—represent an articulation of the Director's discretion: an announcement of the type of considerations the Board must weigh when exercising the Director's delegated discretion in deciding whether to institute IPR. The Director has the discretion to designate these non-dispositive, non-exhaustive factors as precedential because that designation represents a general statement of agency policy.

Plaintiffs frame this case, in part, as being about the benefits of IPR, and complain that access to IPR has become too constrained. *See* Plaintiffs' Renewed Motion for Summary Judgment (ECF No. 153) at 3, 5, 9, 19, 20-21, 23 ("Pls.' Mot. Summ. J."). Whether Congress intended to preference IPR over litigation, and whether the agency acted accordingly, are questions answered in arbitrary-and-capricious review. This Court has already concluded that claim is nonjusticiable, and that conclusion was affirmed by the Federal Circuit. *Apple Inc.*, 63 F.4th at 17-18. Plaintiffs' assertions about these matters are irrelevant to the narrow remaining question here: whether notice-and-comment rulemaking is required when the Director instructs the Board how to exercise discretion on her behalf.

The answer to that question hinges on the language of the Administrative Procedure Act ("APA"), 5 U.S.C. § 553(b)(3)(A). This Court should find that because the *Fintiv* factors are only a "general statement of agency policy" that binds neither the Board nor actors beyond the agency, the designation of the factors is not the sort of agency action that is required to go through notice-and-comment rulemaking. Accordingly, the Director lawfully articulated the *Fintiv* factors. This Court should enter summary judgment for the agency.

I. THE FINTIV FACTORS ARE NOT A SUBSTANTIVE RULE AND THE DIRECTOR WAS NOT REQUIRED TO USE NOTICE-AND-COMMENT RULEMAKING

The APA provides that agencies must use notice-and-comment rulemaking to implement "substantive" rules. *Lincoln v. Vigil*, 508 U.S. 182, 196 (1993) (citing 5 U.S.C. § 553(b)). But the "notice-and-comment requirements . . . do not apply to 'interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice." *Id.* (quoting 5 U.S.C. § 553(b)). Substantive rules are those that are "issued by an agency pursuant to statutory authority' and [have] the 'force and effect of law." *PDR Network, LLC v. Carlton & Harris Chiropractic, Inc.*, 139 S. Ct. 2051, 2055 (2019). One "characteristic inherent in the concept of a 'substantive rule" is that it "affect[s] individual rights and obligations." *Chrysler Corp. v. Brown*, 441 U.S. 281, 302 (1979); *see also Stupp Corp. v. United States*, 5 F.4th 1341, 1352 (Fed. Cir. 2021) ("[Substantive] rules alter the landscape of individual rights and obligations, binding parties with the force and effect of law."). By contrast, general statements of policy "advise the public prospectively of the manner in which the agency proposes to exercise a discretionary power." *Lincoln*, 508 U.S. at 197 (quoting *Chrysler Corp v. Brown*, 441 U.S. 281, 302 (1979) (internal quotation marks omitted)).

Under these standards, the *Fintiv* factors are a general statement of policy, not a substantive rule that requires notice-and-comment rulemaking. They state the manner in which the Director wishes to exercise her discretionary authority over IPR institution. In particular, they state factors the Director wants the Board to consider on her behalf while exercising her discretion. They do not affect individual rights and obligations and accordingly lack the force and effect of law. Plaintiffs contend that the *Fintiv* factors are a substantive rule because they

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limit agency discretion, but that assertion is incorrect and does not establish that the *Fintiv* factors are a substantive rule.

A. THE FINTIV FACTORS DO NOT ALTER THE RIGHTS OF OUTSIDE PARTIES

In determining whether a policy is a substantive rule or a general statement of agency policy, courts consider whether the agency action at issue "effect[s] a change in existing law or policy which affect[s] individual rights and obligations." *Splane v. West*, 216 F.3d 1058, 1063 (Fed. Cir. 2000) (quoting *Paralyzed Veterans of America v. West*, 138 F.3d 1434, 1436 (Fed. Cir. 1998)). The *Fintiv* factors do not affect legally protected individual rights and obligations.⁶

First, neither IPR petitioners' nor patent holders' rights are determined by the institution decision. The institution decision resolves nothing regarding patent validity, and merely initiates an administrative proceeding to revisit that issue. Patent owners have no right to avoid participating in adjudicatory proceedings, *FTC v. Standard Oil Co. of Cal.*, 449 US. 232, 244 (1980), and IPR petitioners have no right to IPR review. *SAS Inst.*, 138 S. Ct. at 1351; *Cuozzo Speed Techs.*, 579 U.S. at 273 ("no mandate to institute review"). The Board can only alter a patent owner's patent claims or estop an IPR petitioner in future proceedings by issuing a final

⁶ Any appellate review regarding plaintiffs' APA claims will be governed by Federal Circuit precedent. The Federal Circuit "review[s] procedural rules following 'the rule of the regional circuit, unless the issue is unique to patent law and therefore exclusively assigned to the Federal Circuit." *Odyssey Logistics & Tech. Corp. v. Iancu*, 959 F.3d 1104, 1108 (Fed. Cir. 2020) (quoting *Madey v. Duke Univ.*, 307 F.3d 1351, 1358 (Fed. Cir. 2002)). "APA claims against the PTO 'raise[] a substantial question of patent law." *Id.* (quoting *Exela Pharma Scis., LLC v. Lee*, 781 F.3d 1349, 1352 (Fed. Cir. 2015)).

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written decision. See 35 U.S.C. §§ 315(e), 318(b). Declining to initiate an inter partes review leaves the patent owner in possession of unaltered patent claims and leaves the IPR petitioner free to challenge those claims in district court. In other words, both parties are left just as they were before the petition was filed. Because denying institution of *inter partes* review does not affect any legal rights, a policy affecting the institution decision likewise does not affect legal rights. The Fintiv factors therefore cannot be a substantive rule requiring notice-and-comment rulemaking.

Plaintiffs also assert that the *Fintiv* factors are a substantive rule because they are an adjustment to the standards by which the agency evaluates IPR petitions. Pls.' Mot. Summ. J. at 18. This proves too much for two reasons. First, this assertion is factually inaccurate: although the *Fintiv* factors provide considerations that must be taken into account in future institution decisions, the Director's unfettered discretion to deny institution under § 314(a) means that there is no "substantive standard by which [the] agency evaluates individual applications" that are eligible for institution. *Id.* The *Fintiv* decision is explicit that the factors are both non-exclusive and non-dispositive. Paper 11 at 5. And second, even if these non-dispositive factors did "change[] the substantive standards" by which the agency evaluated IPR petitions, consideration of those factors does not alter rights or legally protected interests. Pls. Mot. Summ. J. at 18. Otherwise, agency pronouncements like those that "advise the public of how the agency understands, and is likely to apply its binding statutes," would require notice-and-comment rulemaking. Kisor v. Wilkie, 139 S Ct. 2400, 2420 (2019) (citation omitted). But the APA specifically exempts such statements from the notice-and-comment requirements. 5 U.S.C. § 553(b)(3)(A). No doubt Plaintiffs have preferences about which factors the Director (and on delegation, the Board) should weigh. But that does not mean that notice-and-comment

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Plaintiffs' next arguments mix-and-match the Federal Circuit's standing analysis with the APA's statement-of-policy analysis. The Federal Circuit did not comment on whether the *Fintiv* factors constitute a substantive rule or general statement of agency policy. *Apple*, 63 F.4th at 11-12. The panel concluded only that Plaintiffs had alleged facts sufficient for standing. *Id.* The "harm" that Plaintiffs could plausibly allege is linked to the infringement of patent claims, not to the process they are or are not afforded through IPR. "The injury is concrete and legally protected, because of the infringement suit, so the injury and causation requirements for standing are met." *Id.* at 17. The requirement that Plaintiffs establish harm sufficient for Article III standing does not automatically convert to a holding that Plaintiffs' rights are altered by the *Fintiv* factors. The Federal Circuit concluded Plaintiffs had properly pleaded harm sufficient for standing—nothing more, and nothing less.

Plaintiffs also elide the difference between rules that are binding on an agency itself, and rules that the agency intends to bind other actors. *See Coal. for Common Sense in Gov't Procurement v. Sec'y of Veterans Affs.*, 464 F.3d 1306, 1318 (Fed. Cir. 2006) (a substantive rule's change in existing law must be "binding *not only* within the agency but binding on tribunals outside the agency") (emphasis supplied). As Defendant explains further below, the *Fintiv* factors do not compel a specific outcome on institution *even within the agency*. They certainly are not binding on outside actors or tribunals.

Plaintiffs rely on *W.C. v. Bowen*, which is inapposite as a threshold matter. 807 F.2d 1502 (9th Cir. 1987), *opinion amended on denial of reh'g*, 819 F.2d 237 (9th Cir. 1987). There, a class of plaintiffs sued after the Department of Health and Human Services adopted a policy change

that had the effect of scrutinizing the benefits awards made by Administrative Law Judges

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("ALJs"). Id. at 1503-04. Previously, only denials of benefits were appealable. In response to congressional concern that ALJs were too generous, the agency started to review ALJ determinations conferring benefits, in addition to decisions denying benefits. *Id.* Social security, however, is an entitlement. See, e.g., Mathews v. Eldridge, 424 U.S. 319, 332 (1976) ("the interest of an individual in continued receipt of [social security] benefits is a statutorily created 'property' interest protected by the Fifth Amendment"). The plaintiffs in W.C. won because the agency's new procedures had the effect of restricting claimants' access to benefits to which they were statutorily entitled, and because the rule change was "designed to alter ALJ decisions." W.C., 807 F.2d at 1504-05. Unlike social security, no one is entitled to IPR; both § 314 and case law are clear that instituting IPR on eligible petitions is discretionary. And the *Fintiv* factors are not "designed to alter" any of the Board's decisions. Denials of institution therefore cannot fairly be analogized to decisions denying social security benefits.

B. THE DESIGNATION OF THE FINTIV FACTORS AS PRECEDENTIAL DOES NOT REPLACE AGENCY DISCRETION

Plaintiffs nonetheless contend that the *Fintiv* factors constitute a substantive rule because they limit agency discretion, in that the Board cannot refuse to consider the factors when exercising the Director's institution discretion in a case where they apply. That argument misunderstands both the relevant APA principles and the nature of the factors.

The Director's instruction to consider the *Fintiv* factors is binding "on agency officials insofar as any directive by an agency head must be followed by agency employees." Splane, 216 F.3d at 1064. But whether the Director can instruct the Board is not the relevant question in determining whether the *Fintiv* factors are a substantive rule. Rather, Federal Circuit precedent

Here, as Defendant has repeated, the Director has complete and unilateral discretion to deny institution of IPR. Naturally, she may therefore instruct the Board how to "make the institution determinations on her behalf." *Apple*, 63 F.4th at 13. This "guidance is crucial for ensuring that such determinations will overwhelmingly be made in accordance with the policy choices about institution she would follow if she were making the determinations herself." *Id.*And such guidance also "minimiz[es] the number of occasions on which [the Director] has to reverse such determinations, as she may choose to do." *Id.* If the Director has the discretion to choose when and how to institute, or not institute, IPR on eligible petitions—and she does—then she clearly may instruct the Board to follow her guidance and stand in her shoes. But the fact that the Board "must consider" the *Fintiv* factors does not give the factors the force and effect of law; it simply reflects the fact that the governing statutes give the Director (and those to whom she has delegated her authority) control over institution decisions.

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Plaintiffs rely on Ninth Circuit precedent holding that one "factor" in "determin[ing] whether a directive announcing a new policy constitutes a substantive rule or a general statement of policy is the extent to which the challenged directive leaves the agency, or its implementing official, free to exercise discretion to follow, or not to follow, the announced policy in an individual case." *Sacora v. Thomas*, 628 F.3d 1059, 1069 (9th Cir. 2010) (quoting *Colwell v. Dep't of Health & Hum. Servs.*, 558 F.3d 1112, 1124 (9th Cir. 2009) (internal alterations omitted)). Even under this precedent, the *Fintiv* factors do not deprive the agency of discretion in the relevant sense.

Under Ninth Circuit precedent, a substantive rule "effectively replaces agency discretion"

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by "narrowly limit[ing] administrative discretion or establish[ing] a *binding norm* that so fills out the statutory scheme that upon application one need only determine whether a given case is within the rule's criterion." *Id.* (quoting *Colwell*, 558 F.3d at 1124) (emphasis in original) (alterations omitted). By contrast, a general statement of policy "merely provides *guidance* to agency officials in exercising their discretionary power while preserving their flexibility and their opportunity to make individualized determinations." *Id.* (quoting *Colwell*, 558 F.3d at 1124) (alterations omitted). The *Fintiv* factors do not establish a "binding norm" because they do not replace the Board's exercise of the Director's delegated discretion. Rather, they merely guide the Board's decision-making process in determining whether to institute an IPR on the Director's behalf in any instance, without dictating any particular outcome.

Although "[t]he distinguishing line between [substantive] rules and general statements of policy has long been 'fuzzy,' . . . it is clear that" the *Fintiv* factors are only "a policy statement [because] . . . they have no binding legal effect." *Clarian Health W., LLC v. Hargan*, 878 F.3d 346, 357 (D.C. Cir. 2017). Policies that are "not outcome determinative" (*i.e.*, non-dispositive rules) cannot have force of law and therefore cannot be substantive rules. *See id.*, at 358 (criteria governing discretionary decision did not constitute a legislative rule); *Pros & Patients for Customized Care v. Shalala*, 56 F.3d 592, 594–96 (5th Cir. 1995) (concluding a non-exhaustive list of factors to consider when deciding whether to institute enforcement action was not a legislative rule).

The AIA commits to the Director's discretion the decision about whether to institute IPR. See Arthrex, 141 S. Ct. at 1977; Cuozzo Speed Techs., 136 S. Ct. at 2140; see also SAS Inst., 138 S. Ct. at 1356; Oil States Energy Servs., LLC, 138 S. Ct. at 1371. The Director "may not

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authorize" IPR unless "the Director determines that the information presented in the petition . . . and any response filed . . . shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least [one] of the claims challenged in the petition." 35 U.S.C. § 314(a). And, even if the Director does make such a determination, she still may choose not to institute IPR. See id.; see BioDelivery Scis. Int'l, Inc. v. Aquestive Therapeutics, Inc., 935 F.3d 1362, 1365 (Fed. Cir. 2019) (stating the Director has the discretion to deny institution "even when the threshold $[in \S 314(a)]$ is met").

The Director designated the *Fintiv* factors precedential to guide the Board's exercise of this discretion. By their nature, the factors guide, rather than control, the Board's decisionmaking process. The factors do not establish a "binding norm" such that "one need only determine whether a given case is within the rule's criterion." Sacora, 628 F.3d at 1069 (citation omitted). The Fintiv factors direct the Board's attention to certain facts about co-pending district court litigation; they do not offer a plain, formulaic answer to the question of whether to institute IPR. There is no single "criterion" to be considered. As the Board explained in *Fintiv*, the factors announced in that case are "non-dispositive," and the Board may consider any "[o]ther facts and circumstances" it deems relevant. Fintiv, Paper 11 at 5, 16. Further, the Board applies the Fintiv factors with "a holistic view of whether [the] efficiency and integrity of the system are best served by denying or instituting review," and explicitly permits consideration of unenumerated factors, including the strength of the patentability merits. Fintiv, Paper 11 at 6; see June 2022 Guidance, at 3-5. This flexibility, and the opportunity for the Board to make individual institution decisions, demonstrates that the *Fintiv* factors amount to only a general statement of policy guiding exercise of the Director's delegated discretion, not a substantive rule. See Sacora, 628 F.3d at 1069.

Indeed, SOP 2—the policy directive describing the process by which the Director may designate a Board decision as precedential—is clear that it "sets forth *internal* processes and procedures for the administration of [the Board]. It does not create any legally-enforceable rights." SOP 2 at 1 (emphasis supplied). Designating a decision as precedential requires the Board to follow that decision "in subsequent matters involving similar facts or issues." *Id.* at 7. As such, any impact on IPR petitioners or patent owners would have to arise from the Board's consideration of the *Fintiv* factors in individual cases, not the adoption of the factors as a general statement of policy.

Plaintiffs assert that Defendant has "conceded in this case" that "the Board 'must consider' the *NHK-Fintiv* rule in deciding whether to grant or deny an IPR petition where overlapping jurisdiction is pending." Pls.' Mot. Summ. J. at 17 (citation and emphasis omitted). Plaintiffs then jump to the false conclusion that "the *NHK-Fintiv* rule is binding on the Board" and leaves it "with no discretion to follow, or not to follow, it in a particular case." *Id.* (citation omitted). As in earlier briefing, Plaintiffs continue to misunderstand the permissive nature of the *Fintiv* factors. *See* Defendant's Opposition to Plaintiffs' Motion for Summary Judgment (Def.'s Opp.), ECF No. 91, at 7-8 & n.6. A requirement that the Board "must consider" the factors is not the same as a requirement that the Board "must obey" the factors. It is true that the designation of the decisions as precedential means the Board "must consider" the factors. It is not true that this means the factors *per se* dictate the outcome. The only requirement is consideration, after which the Board may choose to—or not to—institute IPR.

The permissive nature of the factors is evident for a second reason: the factors themselves do not have a perspective in favor of, or against, IPR. The six factors together represent an articulation of the Director's discretion to consider co-pending litigation when deciding whether

Finally, the *Fintiv* factors do not limit the Director's exercise of her discretionary authority over institution. The Director, who ultimately holds that statutory authority under the AIA, may overrule the Board's discretionary institution decisions and substitute her own judgment. Moreover, the Director may de-designate the *Fintiv* and *NHK* decisions as precedential at any time. She can also replace the *Fintiv* factors or supplement them with additional instructions, as she did in June 2022. The fact that the Board must consider the Director's instructions while exercising her delegated authority does not mean that the Director's discretion has been limited.

The *Fintiv* factors do not replace, but instead merely guide, agency discretion.

Accordingly, they are the type of guidance that the agency may lawfully adopt without noticeand-comment rulemaking.

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II. ALTHOUGH THE BOARD'S CONSIDERATION OF THE FINTIV FACTORS IS CONSISTENT WITH THE AIA, THIS QUESTION IS NOT PRESENTED BY PLAINTIFFS' REMAINING CLAIM

Plaintiffs' arguments that the Board is somehow acting contrary to congressional intent are misplaced. The question of whether agency policy misapplies congressional intent is one answered in arbitrary-and-capricious review. This Court already dismissed Plaintiffs' arbitrary-and-capricious challenge; this was affirmed on appeal. *Apple*, 63 F.4th at 17-18. The remaining claim—whether the *Fintiv* factors could be designated precedential without notice-and-comment rulemaking—involves a procedural issue divorced from congressional intent regarding the

Plaintiffs' motion frequently conflates the notice-and-comment claim, which is before this Court, and the arbitrary-and-capricious claim, which no longer is. For example, Plaintiffs suggest that the Board denies institution of IPR too frequently, *see* Pls.' Mot. Summ. J. at 9, and argue that application of the *Fintiv* factors "also often led to absurd results." *Id.* These are both articulations of an arbitrary-and-capricious argument. How much IPR is the "right amount" of IPR is unrelated to whether notice-and-comment is required. Similarly, whether consideration of the *Fintiv* factors leads to the results Plaintiffs prefer is not relevant when the only remaining claim is one of notice-and-comment rulemaking. Plaintiffs claim the Director is exercising her discretion in a manner that "thwarts [the] purposes" of the AIA but this, too, is an arbitrary-and-capricious challenge. *Id.* at 21.⁷

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Both this Court and the Federal Circuit have already concluded that Plaintiffs' arbitrary-and-capricious challenge is nonjusticiable. *See Apple*, 63 F.4th at 17-18; Order, at 10-11. These

⁷ Plaintiffs also suggest that certain language in the AIA indicates Congress intended to require notice-and-comment rulemaking, *id.* at 20 (citing 35 U.S.C. § 316). But the only part of § 316 that addresses institution requires the Director to prescribe regulations "setting forth the standards for the showing of sufficient grounds to institute a review under section 314(a)." 35 U.S.C. § 316(a)(2). That provision refers to the minimum requirements for institution, not to the Director's discretionary authority to deny institution once those requirements are met. Nothing in § 316, or any other section, requires the Director to promulgate regulations concerning her discretionary authority to deny institution.

questions, including any arguments about setting an optimal level of IPR institutions, or arguments about "absurd results" or "thwarted purposes," are not currently before this Court. See Pls.' Mot. Summ. J. at 9, 21. This Court should disregard Plaintiffs' arguments that relitigate the already-dismissed arbitrary-and-capricious challenge to the Director's decision-making. **CONCLUSION** For the foregoing reasons, the Court should deny Plaintiffs' Motion, and grant summary judgment for Defendant. Dated: September 21, 2023 Respectfully submitted, BRIAN M. BOYNTON Principal Deputy Assistant Attorney General 11 12 13 14 15 16 17 18 19 20 21 22 24 25 26 27 29 30 BRAD P. ROSENBERG Special Counsel /s/ Hannah M. Solomon-Strauss HANNAH M. SOLOMON-STRAUSS (New York Bar No. 5693890) Trial Attorney U.S. Department of Justice Civil Division, Federal Programs Branch 1100 L Street N.W. Washington, D.C. 20005 Telephone: (202) 616-8198 Facsimile: (202) 616-8470 E-mail: hannah.m.solomon-strauss@usdoj.gov Attorneys for Defendant 31 **CERTIFICATE OF SERVICE** 32 33 I hereby certify that on September 21, 2023, I electronically filed the foregoing document 34 with the Clerk of the Court, using the CM/ECF system, which will send notification of such 35 filing to the counsel of record in this matter who are registered on the CM/ECF system.

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<u>/s/ Hannah M. Solomon-Strauss</u> Hannah M. Solomon-Strauss